K00 1987

SEP - 6 2000

Philips Medical Systems

510(k) SUMMARY

The following information is being submitted in accordance with the requirements of 21 CFR 807.92.

Company Name	:	Philips Medical Systems North America Company.
Address	:	710 Bridgeport Avenue Shelton, CT 06484.
Registration No.	:	1217116
Contact person	:	Peter Altman
Device (Trade) Name	:	**EXPLORER** Gradient (option).
Classification Name	:	Magnetic Resonance Diagnostic Device (MRDD).
Classification	:	Class II.
Product code	:	LNH
Performance standards	:	NEMA voluntary standards, FDA MRDD guidance's, UL and IEC 601 appropriate safety standards and/or draft standards are used.
Common/Usual Name	:	Gradient system **EXPLORER** of **Gyroscan INTERA**.

Predicate Device(s).

EXPLORER GRADIENT is an optional gradient system similar to the optional MASTER gradient system of the Gyroscan INTERA Release 7 series (FDA re.K992533).

Intended Use.

EXPLORER Gradient is intended to allow scans with a maximum gradient amplitude of
60 mT/m providing shorter echo times and enhanced diffusion weighted imaging.

Device Description and Technological Characteristics

EXPLORER Gradient is an optional extension of the possible gradient systems used with the Philips Gyroscan INTERA 1.5T systems. It is based on the same platform as its predicate device MASTER gradient but different technological design.
The gradient coils in the three axes (X, Y and Z) can be utilized in different operation modes:

Philips Medical Systems
North America Company
710 Bridgeport Avenue
P.O. Box 860
Shelton, Connecticut 06484-0917
Tel: (203) 926-7674
Fax: (203) 929-6099

- For the highest slewrate, the gradient amplifiers are driven in a "conventional" fashion, equal to the predicate device MASTER gradient system.
- For a high gradient strength (relevant for diffusion.) the gradient amplifiers are driven is such a way that the electric current through the gradient coil is doubled. This results in twice the gradient amplitude (60 mT/m).
  The gradient coils and the gradient amplifiers are liquid-cooled.

General Safety and Effectiveness.

The option EXPLORER Gradient does not induce any other risks than already indicated for its predicate device MASTER gradient of the Philips Gyroscan INTERA Release 7 series (re. K992533).
The safety parameters are within the limits indicated in:

- *Guidance for the Submission Of Premarket Notifications for Magnetic Resonance Diagnostic Devices (Nov. 14, 1998)*
- *IEC 601-2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis.*

Substantial Equivalence.

EXPLORER Gradient is an optional extension of the possible gradient systems utilized in the Philips Gyroscan INTERA (FDA re. K992533). It is based on the same platform as its predicate device MASTER gradient with the same intended purpose but an enhanced performance, i.e. a higher maximum gradient amplitude.

Conclusion.

The option **EXPLORER GRADIENT** is substantially equivalent to its predicate device MASTER gradient that is already utilized in the Gyroscan INTERA Release 7 series (FDA re. K992533).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2000

Peter Altman
Director of Regulatory Affairs
Philips Medical Systems
North America Company
710 Bridgeport Avenue
Shelton, CT 06484

Re: K001987
Explorer Gradients for Gyroscan MR Intera
Dated: June 28, 2000
Received: June 29, 2000
Regulatory class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Mr. Altman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): K001987
Device Name : **EXPLORER GRADIENT.**

Indication For Use :

The EXPLORER Gradient is intended to allow scans with a maximum gradient amplitude up to 60 mT/m, and herewith gaining shorter echo times and enhanced diffusion weighted imaging. It is an option to the Philips Gyroscan INTERA 1.5T systems

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001987